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PATENT APPLICATION

HEADBAND WITH TENSION INDICATOR

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CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part of Application No. 10/677,742, filed October 1, 2003, the teachings of which are hereby incorporated by reference in their entirety for all purposes.

BACKGROUND OF THE INVENTION

[0002] The present invention relates to headbands, and in particular to headbands that have a tension indicator for indicating when a headband is appropriately stretched and is thus capable of imparting an appropriate level of pressure to a wearer's head.

[0003] Various headband devices are known. These include athletic type headband devices as well as more sophisticated headband devices, such as those used to mount devices carried on the head. Some headband devices are used to apply a certain level of pressure to the region under the headband. Such applied pressures are useful, for example, to support a medical sensor for the wearer of the headband. In such circumstances, there is a need for an improved headband having a tension indicator.

BRIEF SUMMARY OF THE INVENTION

[0004] Embodiments of the present invention are directed to a headband device. In one embodiment, the present invention provides a headband having a low stretch segment sized to fit around a wearer's head; and an elastic segment being smaller than the low stretch segment. The elastic segment has a free end and an attached end, where the elastic segment is attached at its attached end with the low stretch segment, and the free end of the elastic segment is configured to form a closed loop with the low stretch segment around a wearer's head.

[0005] In one aspect, the headband also includes a visual indicator that is configured for monitoring the extended position of the free end of the elastic segment. The visual indicator can be a notch, a line or a marking on the low stretch segment.

[0006] In one aspect, the headband also includes a stop portion, where the stop portion is configured to engage against the elastic segment to limit the stretch of the elastic

segment. In one embodiment, the stop portion has an opening having a width that is smaller than the width of the low stretch segment and the width of the elastic segment.

[0007] In another aspect, the headband also includes a closure mechanism configured to couple the free end of the elastic portion with the low stretch segment to secure the closed loop. The closure mechanism can be a hook and loop closure, a snap, a button, an adhesive, a pin, or combinations thereof.

[0008] In another aspect, the headband also includes a tab portion having a first end and a second end, where the first end of the tab portion is connected with the free end of the elastic portion, and the second end of the tab portion is configured to form a closed loop with the low stretch segment.

[0009] In one aspect, the tab portion is less elastic than the elastic portion.

[0010] In another aspect, the headband also includes a stop portion, where the stop portion is configured to engage against the elastic segment to limit the stretch of the elastic segment. The tab portion also includes an indicator portion between its first end and the stop portion such that the indicator portion when visible indicates that the headband needs re-tightening; and when the indicator portion is not visible it indicates an adequate level of tension corresponding with delivering a pressure in the range higher than the venous pressure and lower than the capillary pressure to the forehead of the wearer.

[0011] In another aspect, the present invention provides a headband for applying pressure to an oximetry sensor on the forehead of a patient. The headband includes a low stretch segment sized to fit around a patient's head, and an elastic segment being smaller than the low stretch segment. The elastic segment has a free end and an attached end, where the elastic segment is attached at its attached end with the low stretch segment. The headband also includes a tab portion having a first end and a second end, where the first end of the tab portion is connected with the free end of the elastic portion, and the second end of the tab portion is configured to form a closed loop with the low stretch segment around a patient's head. The headband also includes a visual indicator that is configured to show the extended position for the elastic segment. The headband also includes a stop portion, where the stop portion is configured to engage against the elastic segment to limit the stretch of the elastic segment. The stop portion has an opening having a width that is smaller than the width of the low stretch segment and the width of the elastic segment. The headband also has a closure mechanism configured to couple the second end of the tab portion with the low stretch segment to secure the closed loop.

[0012] In one aspect, the tab portion includes an indicator portion between its first end and the stop portion such that the indicator portion when visible indicates that the headband needs re-tightening; and when the indicator portion is not visible it indicates an adequate level of tension corresponding with delivering a pressure in the range higher than the venous pressure and lower than the capillary pressure to the forehead of the patient.

[0013] In another aspect, the indicator is a notch, a line or a marking on the low stretch segment.

[0014] For a further understanding of the nature and advantages of the invention, reference should be made to the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] Fig. 1 is a diagram of a forehead oximetry sensor being applied to a patient.

[0016] Fig. 2 is a diagram of a forehead oximetry sensor being held to a patient's forehead with a headband.

[0017] Fig. 3 is a diagram of one embodiment of the headband in accordance with the present invention.

[0018] Fig. 4 is a diagram of an alternate embodiment of the headband in accordance with the present invention.

[0019] Fig. 4A is a top view detail diagram of the crease or fold of Fig. 4.

[0020] Fig. 5 is a front view diagram of an embodiment of the headband in accordance with the present invention shown worn by a user.

[0021] Fig. 6 is a top view diagram of an embodiment of the headband in accordance with the present invention shown in proper tension when worn by a user.

[0022] Fig. 7 is a top view diagram of an embodiment of the headband in accordance with the present invention shown in less than proper tension when worn by a user.

[0023] Fig. 8 is a diagram of an alternate embodiment of the headband in accordance with the present invention.

[0024] Fig. 9 is a diagram of an alternate embodiment of the headband in accordance with the present invention.

[0025] Fig. 10A-E are diagrams showing the method of placing the headband of Fig. 9 on a patient's head.

[0026] Fig. 11 is a top view diagram of the headband of Fig. 9 when placed on a patient's head.

DETAILED DESCRIPTION OF THE INVENTION

[0027] The embodiments of the present invention are directed towards a headband with a tension indicator. Such a headband may be used to support the administration of a health care related service to a patient. Such a service may include the placement of a sensor 101 on a patient's forehead, such as for example, an oximetry sensor (*e.g.*, those manufactured by Nellcor Puritan Bennett, the assignee herein), as is shown in Fig. 1. A typical pulse oximeter measures two physiological parameters, percent oxygen saturation of arterial blood hemoglobin (SpO_2 or sat) and pulse rate. Oxygen saturation can be estimated using various techniques. In one common technique, the photocurrent generated by the photo-detector is conditioned and processed to determine the ratio of modulation ratios (ratio of ratios) of the red to infrared signals. This modulation ratio has been observed to correlate well to arterial oxygen saturation. The pulse oximeters and sensors are empirically calibrated by measuring the modulation ratio over a range of in vivo measured arterial oxygen saturations (SaO_2) on a set of patients, healthy volunteers, or animals. The observed correlation is used in an inverse manner to estimate blood oxygen saturation (SpO_2) based on the measured value of modulation ratios of a patient. The estimation of oxygen saturation using modulation ratios is described in U.S. Patent No. 5,853,364, entitled "METHOD AND APPARATUS FOR ESTIMATING PHYSIOLOGICAL PARAMETERS USING MODEL-BASED ADAPTIVE FILTERING", issued December 29, 1998, and U.S. Patent No. 4,911,167, entitled "METHOD AND APPARATUS FOR DETECTING OPTICAL PULSES", issued March 27, 1990, and the relationship between oxygen saturation and modulation ratio is further described in U.S. Patent No. 5,645,059, entitled "MEDICAL SENSOR WITH MODULATED ENCODING SCHEME," issued July 8, 1997, the disclosures of which are herein incorporated by reference in their entirety. Most pulse oximeters extract the plethysmographic signal having first determined saturation or pulse rate. An exemplary forehead oximetry sensor is described in a co-pending United States Patent Application No. 10/256,245, entitled: "Stacked Adhesive Optical Sensor," the disclosure of which is herein incorporated by reference in its entirety for all purposes.

[0028] The force applied to the oximetry sensor can be a factor in the proper functioning of the sensor. In certain clinical scenarios, a headband 200 is required to be used in conjunction with a forehead sensor 101 (*e.g.*, an oximetry sensor), as is shown in Fig. 2.

Fig. 2 shows the sensor leads extending from the sensor (not shown) outward from beneath the headband. Such clinical scenarios include scenarios where: patient is lying down with his/her head near or below chest level; patient is subject to elevated venous pressure; patient is diaphoretic; patient is moving excessively, such as during exercise; as well as other scenarios where venous pulsations can introduce errors in oximetry calculations. In those scenarios, without a headband, or force on the oximetry sensor, venous pulsations could cause an incorrect interpretation of the waveform, and therefore result in a less than accurate determination of the oxygen saturation and pulse rate values. The headband can be used to apply pressure to the oximetry sensor, thus reducing the effects of venous pulsations. When used to support an oximetry sensor, the amount of force applied by the sensor on the forehead should be greater than the venous pressure, but less than the arteriole pressure. Generally, a good pressure range is one where the applied pressure is higher than venous pressure (*e.g.*, 3-5 mm Hg) and lower than the capillary pressure (*e.g.*, 22 mm Hg). Preferably, this is between 10 mm Hg and 20 mm Hg in the adult patient. The headband in accordance with the embodiments of the present invention may be adjusted for use with any size wearer by using an adjustable closure mechanism, such as for example a hook and loop closure mechanism. Alternately, the headband may be provided in varying sizes, depending on the general size of the wearer's head; for example using a small headband for a neonate, a larger one for a child and an even larger one for an adult wearer. The user can apply a wide range of pressures to the forehead oximetry sensor depending on the amount of tension which has been applied to the headband during its placement around the wearer's head.

[0029] The embodiments of the present invention are intended to alleviate the guesswork by the caregivers by giving them a visual indicator of the proper amount of tension required in the headband during placement around the head. The required tension is related to the pressure being applied by the sensor when it is attached with the patient.

[0030] In one embodiment, shown in Fig. 3, an elastic headband 102 is shown in an unstretched position. A non-elastic fabric 104 is shown attached to the elastics portion 102 along two of its edges 106. The other two edges of the non-elastic portion are not attached to the elastic segment and are thus free to project outward away from the face of the elastic segment. The non-elastic segment is smaller the elastic segment. The non-elastic segment is sized to span a portion of the elastic segment when the elastic segment is stretched. The non-elastic segment is larger than the portion of the elastic segment it spans when the elastic segment is not stretched. As the elastic segment 102 is stretched from its non-stretched position, the non-elastic portion is pulled at its edges 106 along with the

stretching elastic segment 102 until the elastic portion between the edges has stretched to a length equal to the length of the non-elastic portion. The headband also includes closure mechanisms (not shown), which are described below in conjunction with Fig. 4. Fig. 5 shows a front view diagram of an embodiment of the headband in accordance with the present invention shown worn by a user. It is noted that the headband may be used to hold and impart a pressure against a sensor, such as an oximetry sensor applied to a patient's forehead, as shown in Fig. 2. For clarity in describing the tension indicator, such a sensor is not shown in Figs. 5-7. Fig. 6 is a top view diagram of an embodiment of the headband 102 in accordance with the present invention shown in proper tension when worn by a user. As is shown in this figure, when the headband is properly tightened, the pressure indicator portion 104 is pulled tight across the elastic portion 102, thus not providing a visual indication that the headband needs to be retightened. On the other hand, Fig. 7 shows a top view diagram of an embodiment of the headband in accordance with the present invention shown in less than proper tension when worn by a user. As is shown in Fig. 7, when a less than adequate pressure is being applied by the headband to a user's forehead, or when the headband is not tight enough, the indicator 104 projects out from the surface creating a loop which provides a visual cue that the headband needs retightening.

[0031] When the headband is not stretched there is an amount of slack between the non-elastic and elastic portions. When the headband is stretched, the slack in the non-elastic strap is eliminated, giving the visual indication that the headband stretch is sufficient. The headband is chosen to be long enough to fit around the head of a user (or patient). The elastic material may be made of any suitable fabric, such as an open cell urethane foam. The non-elastic strap, which is shorter than the elastic portion is sewn or attached otherwise (*e.g.*, adhesively, etc.) onto the elastic headband at a spacing that is less than the lengths of the non-elastic portion. The non-elastic material may be made of any suitable fabric, such a Dacron-type fabric.

[0032] Fig. 4 is a diagram of an alternate embodiment of the headband in accordance with the present invention. An elastic headband 102 is shown in an unstretched position. A non-elastic fabric 104 is shown attached to the elastics portion 102 along two of its edges 106. The other two edges of the non-elastic portion are not attached to the elastic segment and are thus free to project outward away from the face of the elastic segment. The non-elastic segment 104 is smaller the elastic segment 102. The non-elastic segment is sized to span a portion of the elastic segment when the elastic segment is stretched. The non-elastic segment is larger than the portion of the elastic segment it spans when the elastic

segment is not stretched. As the elastic segment 102 is stretched from its non-stretched position, the non-elastic portion is pulled at its edges 106 along with the stretching elastic segment 102 until the elastic portion between the edges has stretched to a length equal to the length of the non-elastic portion.

[0033] Fig. 4 also shows the non-elastic portion to include a permanent crease or a fold 110. As shown in Fig. 4A, such a fold 110 may be made by overlapping the non-elastic portion to form a fold and then heat pressing or heat sealing the fabric to form a permanent fold or crease. In one embodiment, the fold or crease is made in the middle of the inelastic segment, which causes it to project outward in a sharp, angular fashion as the elastic band 102 retracts or relaxes. In operation, it has been shown that the sharp, angular crease or fold acts as a mechanical amplifier and provides a more distinct visual cue and better sensitivity as to when the threshold of minimal headband tension has been passed. The creased tension indicator 110 exhibits increased sensitivity to a loss in headband tension by projecting further away from the elastic band in a skewed fashion. The creased tension indicator 110 provides a more pronounced visual cue both from the perspective of looking directly at the forehead and from looking down at the top (edge) of the headband. The material chosen for the inelastic portion having a fold or a crease can be similar to the noncreased or nonfolded inelastic material. In addition, a material such a polyester webbing material, which is capable of holding a fold or a crease, may also be used. The elastic material may be made of a material as is described above, or made using other suitable material such as a terry band.

[0034] When the headband is not stretched there is an amount of slack between the non-elastic and elastic portions. When the headband is stretched, the slack in the non-elastic strap is eliminated, giving the visual indication that the headband stretch is sufficient.

[0035] Also shown in Fig. 4, and applicable to the embodiment described in conjunction with Fig. 3, is the closure device 108. One such closure device is a hook and loop type closure. The headband in accordance with the embodiments of the present invention may use other closure mechanisms such as snaps, buttons, adhesives, pins, or combinations thereof, as well as others known to those of skill in the relevant arts. Alternately, the headband may be a pre-formed loop, without a separate closure mechanism.

[0036] The headband described above includes a sensor attachment pressure indicator. As described above, the headband may be used to allow a sensor's attachment pressure with the patient's tissue location (*e.g.* forehead, and so on) to be chosen which is

greater than venous pulsations (*e.g.*, 5-10 mm Hg) but less than a maximum amount (*e.g.*, 30 mm Hg, or so). As described above, such a pressure indicator is attached with the headband. Alternately, the pressure indicator may be attached with the sensor, such as an oximetry sensor. One embodiment of the pressure indicator is a tension indicator as described above with reference to Figs. 3-4. Other pressure indicating means include pressure or force sensors small and light enough to be included with either the sensor or the headband assembly.

[0037] The information provided by the pressure indicator may be used to help establish an acceptable windows of pressure for the sensor's attachment with a patient. The acceptable window of pressure may also be enhanced to include the affects of the patient's head elevation relative to the patient's heart.

[0038] Additionally, the concept of using a headband to ensure an acceptable sensor attachment pressure is extendible to other patient body locations; locations where a sensor attachment pressure can help provide a more accurate sensor reading.

[0039] An alternate embodiment of the tension or pressure indicating headband in accordance with the present invention is shown in Fig. 8. As is shown in Fig. 8, the headband includes an inelastic portion 604 and an elastic portion 602. The tension indicating portion 606 is also made of an inelastic material. The tension indicating portion 606 may be a creased or folded as described in conjunction with Fig. 4 or as is shown uncreased or unfolded as described in conjunction with Fig. 3. The description of the closure devices and how the elastic and inelastic portions are attached to one another are also set forth above. In this embodiment, the main stretchable portion is elastic portion 602. Once the headband has been stretched such that section 602 is stretched to match the length of section 606, the headband's stretch will be limited. This embodiment by having a shorter elastic portion limits the extension of the headband and hence limits the range of pressures that can be applied by the headband against a user's forehead or the sensor applied to a user's forehead.

[0040] Fig. 9 is an exemplary diagram of an alternate embodiment of the headband in accordance with the present invention. The headband may be used for the purpose of applying a small, controlled amount of pressure against the forehead of its wearer. As set forth above, when used to support an oximetry sensor, the amount of force applied by the sensor on the forehead should be greater than the venous pressure, but less than the arteriole pressure. Generally, a good pressure range is one where the applied pressure is higher than venous pressure (*e.g.*, 3-5 mm Hg) and lower than the capillary pressure (*e.g.*, 22 mm Hg). Preferably, this is between 10 mm Hg and 20 mm Hg in the adult patient. The

headband in accordance with the embodiments of the present invention may be adjusted for use with any size wearer by using an adjustable closure mechanism, such as for example a hook and loop closure mechanism. Alternately, the headband may be provided in varying sizes, depending on the general size of the wearer's head; for example using a small headband for a neonate, a larger one for a child and an even larger one for an adult wearer. The user can apply a wide range of pressures to the forehead oximetry sensor depending on the amount of tension which has been applied to the headband during its placement around the wearer's head. In one embodiment, the different head sizes of the wearer's are accommodated by providing a suite of different sized headbands; starting with the smallest and graduating to larger sized ones; all having common features as described herein. In another embodiment, a hook and loop type closure device is configured such that the entire back side of the low stretch band (described below) is capable of engaging an end of the headband having the mating hook and loop surface. In this manner, a one size headband is enabled to accommodate any size head. Further details are described below.

[0041] The embodiment shown in Fig. 9 enables a clinician to accurately and consistently apply the headband with the proper tension in an intuitive manner as described below. As shown in Fig. 9, the headband includes a substantially inelastic, or low stretch band 202 having a closure device 208 on or near its end and preferably on a portion of or the entire outer surface thereof. One such closure device is a hook and loop type closure. The headband in accordance with the embodiments of the present invention may use other closure mechanisms such as snaps, buttons, adhesives, pins, or combinations thereof, as well as others known to those of skill in the relevant arts. The inelastic or low stretch band 202 can be made of any type of low-stretch fabric, such as a Nylon, polyester or equivalent materials, including those described above.

[0042] The headband also includes an elastic segment 204 of a specific length, to provide a specific spring force once stretched, attached at one end 203 to the outer facing side of the low stretch material (i.e. band 202) that wraps around the patient's head. The attachment of the elastic segment 204 to band 202 at 203 may be achieved by sewing the segment 204 at 203 to 202. Alternately, the segment 204 may be adhesively attached to band 202 at 203. At the other, free end, 205 the elastic segment 204 is configured to be attached with a segment of band 202 using a closure device 208, as described above (*e.g.*, inelastic material that has a patch of Velcro™ hook material). In one embodiment, the free end 205 of the elastic segment is attached with a low stretch portion or tab 206, which attaches with a segment of band 202 using a closure device 208 to form a closable loop. The band 206 slips

through slots in the band 202 at the stop 207, in a manner similar to a belt through a loop. To apply a proper tension, and hence a proper amount of pressure against the skin, to the low stretch material band 202 wrapped around the head, the elastic segment 204 is stretched a controlled distance, and then fastened to the low stretch strip 202 using the closure device 208. The stretch of the elastic segment 204 is controlled, as it meets a physical stop. In one embodiment, the physical stop is provided by having the width of the elastic portion 204 sized slightly larger than the opening of the stop 207 in the band 202, and thus once stretched a certain distance, the elastic portion 204 meets a physical stop 207. The stop 207 may be an opening in the band 202 that is slightly smaller in width than the elastic portion 204. Alternately, the stop may be provided by a narrow band similar in shape and function to a belt loop that is sewn on or attached with the band 202. By stretching and fastening the elastic portion 204 with the band 202, the tension in the elastic segment 204 is transferred to the entire low stretch strip that is wrapped around the patient's head. This controlled tension, in turn, translates into a controllable pressure against the patient's forehead skin. In other words, proper tension in the band and hence proper pressure against the forehead of the patient is achieved by wrapping the band 202 around a patient's head; then pulling on the elastic segment directly or via a pulling force on the member 206 to extend the elastic segment 204 until its edge 210 meets the stop 207, and then securing the free end of segment 206 against the band 202 using the closure device 208.

[0043] The headband also includes a visual indicator that is used to monitor the stretch of the elastic portion 204. In one embodiment, the tab 206 includes a visible or indicator portion 211 between the free end of the elastic portion 205 and the stop 207, such that when the headband is properly tensioned, the elastic portion 204 is stretched and thus portion 211 is no longer visible, as the elastic portion 204 abuts against the stop 207. Alternately, headband includes visual indicator 212 (shown in Fig 10D' and 10D"), that enable the visual monitoring of the edge of the free end of the elastic segment 204 against the indicator 212, as the segment 204 is stretched. While the indicator 212 is shown as a notch, it can be a line, or any other suitable marker. The headband described herein provides structures that monitor and/or control the stretch of the elastic segment 204. The stretch of the elastic segment is controlled by the stop 207. The stop 207 ensures that the elastic segment's stretch is limited, as describe above. For example, a clinician is prevented from over stretching the elastic segment, since the free edge of the elastic segment will meet against the stop 207 once it is fully stretched. The visual indicator 211 or 212 enable the monitoring of the amount of the stretch of the elastic segment. In addition, the adequacy of

the tension or stretch of the segment is monitored visually by observing either the indicator 211 or the position of the free edge of the segment against the indicator 212. So, for example, once the headband has been properly applied, it is expected that the headband or portions thereof may relax and in which case the visual indicators will show that the headband needs re-tensioning.

[0044] Figs. 10A-E are diagrams showing the method of placing the headband of Fig. 9 on a patient's head. For ease of description, it is assumed that the patient or headband wearer is lying down on his (or her) back on a surface and facing up. As shown in Fig. 10A, first the headband is placed under the patient's head with the elastic segment side facing down and on the same side as that of a forehead oximetry sensor 300. For ease of placement, it is preferred to allow the length of the band to extend more on the elastic segment side. Next, as shown in Fig. 10B, the shorter end is rolled towards the patient's forehead. Next, as shown in Fig. 10C, the elastic segment side is rolled over the patient's forehead covering the sensor 300. It may be preferable to provide a sensor design outline on the elastic portion of the headband, in which case it is preferred to align the sensor outline on the elastic band portion of the forehead sensor approximately with the sensor 300. Next, as shown in Fig. 10D, the tab 206 is pulled until the elastic portion 204 reaches the stop 207 and indicator or visible portion 211 of the band is no longer visible. Note that the tab 206 has a portion 211 (*e.g.*, indicator portion) that is partially visible between the elastic portion 204 and the stop 207 in Fig. 10C, when the band in not adequately stretched, and the same tab portion 211 (*e.g.*, indicator portion) is no longer visible between the elastic portion 204 and stop 207 when the elastic portion is adequately stretched, as shown in Fig. 10D and 10E. Alternately, as shown in Figs. 10D'-D", after the elastic segment side is rolled over the patient's forehead covering the sensor 300, the tab 206 is pulled until the elastic segment 204 reaches the position mark or indicator 212. An adequately stretched headband is enabled to impart an adequate tension in the headband and hence an adequate pressure against the forehead and the sensor that is placed between the forehead and the headband. Therefore, when there is no tab portion 211 visible between the elastic portion 204 and the stop 207, or when the elastic segment is properly aligned with the indicator 212, or when the elastic portion has been adequately stretched against its stop, the clinician has an indicator that a proper pressure is being applied to the wearer's forehead.

[0045] Fig. 11 is a top view diagram of the headband of Fig. 9 when placed on a patient's head with an adequate tension. As can be seen, band 202 is wrapped around the

patient's head, elastic portion 204 is adequately stretched and fastened with the band 202 via tab portion 206.

[0046] As will be understood by those skilled in the art, the present invention may be embodied in other specific forms without departing from the essential characteristics thereof. These other embodiments are intended to be included within the scope of the present invention, which is set forth in the following claims.